

NIH CLINICAL CENTER NURSING & PATIENT CARES SERVICES
CRN ROLE COMPETENCY VALIDATION

Name: _____ Manager or Designee: _____
 Work Area: _____ Primary Preceptor: _____
 Hire Date: _____ Competency Date: Met _____ Not Met: _____

Reason for validation: • Orientation • Re-validation • PI Follow-up • Other _____

Key: 1 = No knowledge/No experience 3 = Knowledge/Done with assistance **Circle method used for validation:** D = Demonstration DR = Documentation Review V = Verbalization
 2 = Knowledge/No experience 4 = Knowledge/Done independently T = Test/Quiz O = Other (specify)

Competency: Protocol Integrity – Maintains the integrity of biomedical research protocols.

Behavioral Indicators	Self Evaluation				Assessment Method	Validator's Signature/Date		Learning Resources	Comments
						Met	Not Met*		
1. Describes guidelines for ethical practice in nursing as defined by the ANA Code for Ethics and the Federal Regulations for Protection of Human Subjects.	1	2	3	4	V			NPCS Orientation Unit Orientation	
2. Identifies the nurse's responsibility in the witnessing of an informed consent/assent.	1	2	3	4	V			Work Area Protocol Guidelines ANA Code for Ethics http://www.nursingworld.org/ethics/code/ethicscode150.htm	
3. Assesses for completeness of patient's protocol informed consent/assent.	1	2	3	4	D			MAS: Informed Consent (M77-2)	
4. Identifies resources for protocol information and support.	1	2	3	4	D, V			Consent Process in Research Involving Impaired Subjects (M87-4)	
5. Follows protocol requirements.	1	2	3	4	D			Research involving Children and Children's Assent to Research (M92-5)	
6. Demonstrates proper labeling and collection of research specimens.	1	3	3	4	D			Research Involving Human Subjects at the Clinical Center: Structure and Process (M93-1)	
7. Maintains knowledge of revisions and amendments to protocols.	1	2	3	4	D, DR, V			Guidelines for Blood Drawn for Research Purposes in Clinical Center (M95-9)	
8. Correctly documents protocol data.	1	2	3	4	DR			Participation of Clinical Research Volunteers in NIH Clinical Center Biomedical Research Protocols (M99-1)	
9. Advocates for the patient, family, and members of the biomedical research team.	1	2	3	4	D, DR			Office for Human Subject Protections http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm Clinical Bioethics: www.bioethics.nih.gov/ Experience with preceptor	

Action Plan for Competency Achievement

Targeted Areas for Improvement (Behavioral Indicators):

Educational Activities/Resources Provided:

“Hands on” practice planned with preceptor, unit educator, CNS, nurse manager:

Re-evaluation date: _____

By: _____

Competency Met

Competency Not Met

Next Step: _____